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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/648,459	08/26/2003	Thomas Yung-Hui Chien	1001.2205101	5094
28075 7590 09/17/2008 CROMPTON, SEAGER & TUFTE, LLC 1221 NICOLLET AVENUE SUITE 800 MINNEAPOLIS, MN 55403-2420				
EXAMINER				
GETTMAN, CHRISTINA DANIELLE				
ART UNIT		PAPER NUMBER		
3734				
MAIL DATE		DELIVERY MODE		
09/17/2008		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/648,459

**Applicant(s)**

CHIEN ET AL.

**Examiner**

CHRISTINA D. GETTMAN

**Art Unit**

3734

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 24 September 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,3-10 and 12-32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-10 and 12-32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1,4-10,12-15,18,19,21,23-28 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stiger, et al.-6589274 in view of Barry-5439446.

Stiger discloses a stent delivery catheter having an outer tube with a distal tip 16,40, an inner tube 18 with a tapered distal tip 38; a balloon 52 extending between the distal ends of the two tubes, a stent 42 crimped to the balloon and radiopaque markers 74 inside the balloon. The diameter of the proximal end of the distal tip of the inner tube and the diameter of the distal tip of the outer tube are both larger than the diameter of the stent when unexpanded as seen in fig. 2. Stiger also discloses using a fluid to expand the balloon. However, Stiger does not disclose using a heating element to inflate the balloon and, in turn, heat the stent. Barry discloses providing a heating

element inside the balloon of the stent delivery catheter (col. 9, lines 20-27). It would have been obvious to have provided Stiger with a heating means in order to heat the fluid in the balloon, inflate the balloon, and also heat the stent. Barry also discloses a stent made out of Nitinol for the purpose of providing a self-expanding stent. As recited in the claims of the present application, the stent is made out of Nitinol. Since the stent of Barry is made of the same material, it has the capability of acting in the same manner, expanding when introduced to heat, as that of the application.

Claims 3 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stiger, et al.-6589274 in view of Barry-5439446 as applied to the claims above, and further in view of Kasprzyk-'694.

Stiger as modified by Barry make obvious the invention as claimed with the exception of the heater being a coil. Kasprzyk discloses a coil heating element in the balloon of a balloon catheter. It would have been a mere known alternative and equivalent heating mechanism to employ the coil of Kasprzyk instead of the heater of Barry.

Claims 16,17,29 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stiger, et al.-6589274 in view of Barry-5439446 as applied to the claims above, and further in view of Harada-5037427

Stiger as modified by Barry makes obvious the invention as claimed with the exception of the cooling of the stent. Harada discloses that it was known to provide cooling saline for a stent delivery catheter in order to keep it in its reduced configuration.

Claims 22 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stiger, et al.-6589274 in view of Barry-5439446 as applied to the claims above, and further in view of Lau-6309412.

Stiger as modified by Barry makes obvious the invention as claimed with the exception of the outer sheath over the stent. Lau discloses that it was known to use an outer sheath over a stent to protect it during insertion. It would have been obvious to have used an outer sheath over the stent delivery balloon catheter of Stiger as modified by Barry, in order to protect the stent and balloon during it's insertion through the vasculature.

#### ***Response to Arguments***

Applicant's arguments filed September 24, 2007, have been fully considered but they are not persuasive. Applicant argues that neither Stiger nor Barry discloses or suggests a stent delivery system having an expandable stent made of a stent material having a shape memory transition temperature. Applicant further argues that neither Stiger nor Barry discloses or suggests a heating element for heating the stent to an elevated temperature in order to expand the stent. Applicant argues that Barry's heating element is used to coagulate the aneurysmal wall and not to expand the stent. Even further, the Applicant argues that the combination of the two references if based on improper hindsight. Examiner respectfully disagrees.

As mentioned in the above rejection, Barry discloses deploying a stent that could be made out of Nitinol. Applicant recites in the claims that the self-expanding stent can be made of Nitinol. Since the reference discloses the same material that is recited in

the claims, the stent of Barry is capable of acting in the same manner as the stent disclosed in the application. Nitinol is well-known in the art to be a self-expanding stent material that expands upon being heated, usually by body temperature. Applicant also admits that self-expanding stents are known in the art (page 2). Barry discloses using a heating element to heat liquid that is within the interior of balloon. Barry also discloses that in activating the heating elements, the stent is also heated. As a result, if a Nitinol stent is used with Barry, heating of the stent would cause the stent to expand in the vessel. The Examiner also notes that it would have been reasonable to try the same method for a different purpose. Although Barry discloses heating being used to treat an aneurysm, heating could also be used for another purpose. The combination of the elements is proper. The balloon of Stiger is inflated by injecting fluid into the interior of the balloon. The balloon of Barry is inflated by heating the fluid that is already in the interior of the balloon. Since both references describe a way to inflate a balloon to further deploy a stent, they are properly combinable.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTINA D. GETTMAN whose telephone number is (571)272-3128. The examiner can normally be reached on Monday-Thursday 6:45 am to 3:15 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Christina D Gettman/  
Examiner, Art Unit 3734  
571-272-3128

/Todd E Manahan/  
Supervisory Patent Examiner, Art Unit 3731